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EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Application No.

10/608,987

Applicant(s)

HAWKINS, JOHN R.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 13-20, 22-24, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 13-20, 22-24, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 20 is objected to because it depends on canceled claim 12. In this office action, claim 20 has been assumed to depend from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 11, 24 and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11, the phrase "core has a lower hardness," renders the claim vague and indefinite since it is unclear which hardness the hardness of the core is being compared to.

In claim 24, the phrase "core has a lower hardness," and the phrase "sidewall of the outer shell has a higher hardness," renders the claim vague and indefinite since it is unclear which hardness the hardness of the core is being compared with.

In claims 28-29, the limitations, "lower thickness" and "larger thickness" render the claim vague and indefinite since it is unclear what thickness the upper wall thickness and the side wall thickness is being compared to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-4, 9, 13-17, 20 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stubstad et al. (US 3,867,728) in view of Marino et al. (US 2004/0133278A1).

Stubstad et al. disclose a prosthetic element 15D shaped as a spinal disc with a core (71) and a silicone covering or shell (70, 72, 76) on all exposed surfaces (Figures 11-15, col. 2, lines 41-61, col. 3, lines 1-11 and col. 10, lines 41-58).

Stubstad et al. disclose all elements of the claimed invention except that the upper surface of the upper wall of the outer shell or the lower surface of the lower wall of the outer shell has a coefficient of friction against bone of at least 0.5.

Marino et al. teach adjusting the coefficient of friction of the contact surface of a component so that the component has a desired movement relative to an adjacent component (para [0014] and [0068]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have adjusted the coefficient of friction of the upper surface of the upper wall and the lower surface of the lower wall against bone to at least 0.5 or to have provided a surface roughness of no more than 0.15 mm to the upper surface of the upper wall, to attain a desired movement of the device of the combination of Stubstad et al and Marino et al. relative to bone, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 3-4 and 14-15, Stubstad et al. disclose that the prosthetic element is cast into a proper shape (col. 5, lines 53-66). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the Stubstad et al. with different shapes and sizes, since applicant has not disclosed that these shapes solve any particular problem or are anything more than numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of shaping an intervertebral prosthesis to match the properties of a normal disc. In re Dailey and Eilers, 149 USPQ 47 (1966).

Regarding claims 7-8, Stubstad et al. disclose that the prosthetic element may be reinforced (with intermediate layers) or unreinforced (without intermediate layers).

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Regarding claim 9, Marino et al. teach providing radiological or "radio opaque" markers in the components of an implant "invisible" to radiological techniques (para [0014]). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radio opaque marker in the outer shell or core, as taught by Marino et al., in order to make the implant of the combination of Stubstad et al. and Marino et al. visible during radiological techniques.

Claims 5-6, 11 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stubstad et al. (US 3,867,728) and Marino et al. (US 2004/0133278A1), as applied to claim 1, further in view of Parsons et al. (US 5,545,229).

Regarding claims 5-6, the combination of Stubstad et al. and Marino et al. disclose all elements of the claimed combination except for the outer shell having a variable thickness.

Parsons et al. teach varying thickness of the outer shell, the hardness of the outer shell and the inner core of an intervertebral spacer or prosthesis to match the mechanical properties of a normal disc. Parsons et al. also teach that the varying hardness can be attained by utilizing the same material with various degrees of stiffness, i.e., different grades of the same material (col. 4, lines 7-65).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an outer shell of variable thickness or hardness, as taught by Parsons et al. to match the properties of the prosthesis of the combination of Stubstad et al. and Marino et al. to that of a normal disc.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the outer shell in the prosthesis of the combination of Stubstad et al. and Marino et al. and Parsons et al. with a lower thickness than the sidewall or the core with a lower hardness than the outer shell, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stubstad et al. (US 3,867,728) and Marino et al. (US 2004/0133278A1), as applied to claim 1, further in view of Fraser et al. (US 6,592,624).

The combination of Stubstad et al. and Marino et al. disclose all elements of the claimed invention except for recesses on the upper or lower surfaces.

Fraser et al. teach recesses or "blind bores" 26, 26A in the upper and lower surfaces of an implant serving as a visual key for to indicate the surface of the implant (i.e., whether an upper or a lower surface) (Figures 1 and 7 and col. 3, lines 2-14).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided recesses in the upper and lower surfaces of the implant of the combination of Stubstad et al. and Marino et al., as taught by Fraser et al., as a visual key to indicate the surface of the implant.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on November 1, 2004 with respect to claims 1-9,11,13-20, 22-24 and 28-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*
February 5, 2005


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